

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

ACERTA PHARMA B.V. et al.,

Plaintiffs,

v.

ALEMBIC PHARMACEUTICALS
LIMITED

Defendants.

C.A. No. 22-154-RGA

ACERTA PHARMA B.V. et al.,

Plaintiffs,

v.

NATCO PHARMA LIMITED, et al.,

Defendants.

C.A. No. 22-155-RGA

ACERTA PHARMA B.V. et al.,

Plaintiffs,

v.

CIPLA LIMITED, et al.,

Defendants.

C.A. No. 22-162-RGA

ACERTA PHARMA B.V. et al.,

Plaintiffs,

v.

MSN PHARMACEUTICALS INC.,

Defendant.

C.A. No. 22-163-RGA

ACERTA PHARMA B.V. et al.,

Plaintiffs,

v.

SANDOZ INC.,

Defendant.

C.A. No. 22-164-RGA

[PROPOSED] SCHEDULING ORDER

This ____ day of May, 2022, the Court having conducted an initial Rule 16(b) scheduling conference pursuant to Local Rule 16.1(b) on May 11, 2022, and the parties having determined after discussion that the matter cannot be resolved at this juncture by settlement, voluntary mediation, or binding arbitration;

IT IS ORDERED that:

1. Consolidation. The above captioned actions are consolidated for all purposes including trial, and all papers shall be filed in Civil Action No. 22-154-RGA. Notwithstanding consolidation, the Court recognizes that there may be issues regarding infringement unique to certain defendants and that separate trial days for infringement may be necessary.

2. Rule 26(a)(1) Initial Disclosures. The parties have agreed to exchange their initial disclosures pursuant to Federal Rule of Civil Procedure 26(a)(1) within 60 days of the date of this Order.

3. Joinder of Other Parties and Amendment of Pleadings. **[Plaintiffs' Position:** All motions to join other parties, and to amend or supplement the pleadings, shall be filed on or before January 9, 2023.] **[Defendants' Position:** All motions to join other parties, and to amend or supplement the pleadings, shall be filed on or before December 15, 2023.]

4. Discovery.

a. Fact Discovery Cut-Off. All fact discovery in this case shall be initiated so that it will be completed on or before February 12, 2024.

b. Document Production. Document production shall be substantially complete by June 12, 2023.

c. Contentions. The parties shall furnish their initial disclosures and initial patent discovery under Paragraphs 3 and 4 of the Court's Default Standard for Discovery, Including Discovery of Electronically Stored Information ("the Default Standard") in accordance with the provisions therein.

- i. Each Plaintiff Group¹ shall make its disclosures under Paragraph 4(a) of the Default Standard within 45 days of the date of this Order.
- ii. **[Plaintiffs' Position:]** Each Defendant Group² shall produce its core technical documents under Paragraph 4(b) of the Default Standard including a complete copy of the Defendant Group's Abbreviated New Drug Application ("ANDA"), no later than 45 days after service of Plaintiffs' Paragraph 4(a) disclosures. At the same time each Defendant Group produces its core technical documents, the Defendant Group shall also produce the Drug Master File ("DMF") for the acalabrutinib active pharmaceutical ingredient ("API") used in its proposed ANDA products, to

¹ The Plaintiff Groups in this action are: (1) Acerta Pharma B.V., AstraZeneca UK Limited, AstraZeneca Pharmaceuticals LP, and AstraZeneca AB; and (2) Merck Sharp & Dohme B.V.

² The Defendant Groups in this action are: (1) Alembic Pharmaceuticals Limited; (2) Natco Pharma Limited and Natco Pharma, Inc.; (3) Cipla Limited and Cipla USA, Inc.; (4) MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited; and (5) Sandoz Inc.

the extent the DMF is in the Defendant Group's possession, custody, or control, or the Defendant Group is able to obtain the DMF pursuant to a contractual right to the DMF with the DMF holder. If the Defendant Group is not in possession, custody, or control of the DMF, and cannot obtain the DMF pursuant to a contractual right with the DMF holder, the Defendant Group shall inform Plaintiffs of that fact and identify the DMF holder at the same time it produces its core technical documents.] [**Defendants' Position:** Each Defendant Group³ shall produce its core technical documents under Paragraph 4(b) of the Default Standard no later than 45 days after service of Plaintiffs' Paragraph 4(a) disclosures. For the purposes of clarity, the "core technical documents" for each Defendant Group are limited to a complete copy of the Defendant Group's Abbreviated New Drug Application ("ANDA").]

- iii. Each Plaintiff Group and each Defendant Group shall make their initial disclosures under Paragraph 3 of the Default Standard no later than 45 days after service of Plaintiffs' Paragraph 4(a) disclosures (i.e., on the same day that each Defendant Group is to make its Paragraph 4(b) disclosures, as above).
- iv. Each Plaintiff Group shall make its disclosures under Paragraph 4(c) of the Default Standard no later than 45 days after service of Defendants' Paragraph 4(b) disclosures;

³ The Defendant Groups in this action are: (1) Alembic Pharmaceuticals Limited; (2) Natco Pharma Limited and Natco Pharma, Inc.; (3) Cipla Limited and Cipla USA, Inc.; (4) MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited; and (5) Sandoz Inc.

- v. Each Defendant Group shall make its disclosures under Paragraph 4(d) of the Default Standard no later than 45 days after service of Plaintiffs' Paragraph 4(c) disclosures.

d. Samples. [**Plaintiffs' Position:** At the same time Defendants produce their core technical documents under Paragraph 4(b) of the Default Standard, Defendants shall also disclose in writing to Plaintiffs whether each Defendant Group is able to produce reasonable quantities of unexpired samples (unexpired as of the entry of this Order) of the Defendant Group's ANDA product and API, to the extent such samples are in the Defendant Group's possession, custody, or control, or the Defendant Group can obtain such samples pursuant to a contractual right with a supplier. No later than 10 days after service of Defendants' Paragraph 4(b) disclosures, each Defendant Group shall meet and confer with Plaintiffs regarding the production of reasonable quantities of unexpired samples (unexpired as of the entry of this Order) of the Defendant Group's ANDA product and API to the extent such samples are in the Defendant Group's possession, custody, or control, or the Defendant Group can obtain such samples pursuant to a contractual right with a supplier; such meet and confer will include discussion on the quantity of samples to be produced, the location of production, and the conditions under which the samples should be shipped.] [**Defendants' Position:** To the extent Plaintiffs serve a Defendant Group with a Request for Production seeking samples of finished drug product, API, or both, Defendants and Plaintiffs shall meet and confer in good faith regarding the quantity of samples to be produced (if any), the location of production, and the conditions under which the samples should be shipped.]

e. Requests for Admission. The Plaintiff Groups will coordinate with one another and may jointly serve up to **50** requests for admission on each Defendant Group. The Defendant Groups will coordinate with one another and may jointly serve up to **50** requests for admission on

each Plaintiff Group. In addition, each Plaintiff Group may serve on each Defendant Group up to **50** individualized requests for admission, and each Defendant Group may serve on each Plaintiff Group up to **50** individualized requests for admission. Any additional requests for admission may only be served by agreement of the parties or with leave of Court. Any requests for admission directed to the authentication or admissibility of documents are exempt from the limitations above. The parties will strive to agree on authentication where possible.

f. Interrogatories. The Plaintiff Groups may jointly serve up to **25** interrogatories on each Defendant Group. The Defendant Groups may jointly serve up to **25** interrogatories on each Plaintiff Group. In addition, each Plaintiff Group may serve on each Defendant Group up to **10** individualized interrogatories, and each Defendant Group may serve on each Plaintiff Group up to **10** individualized interrogatories. The parties will confer in good faith to the extent the circumstances warrant any additional interrogatories.

g. Depositions.

i. Limitation on Hours for Deposition Discovery. [**Plaintiffs' Position:** Plaintiffs collectively are limited to 70 hours of taking fact deposition testimony upon oral examination per Defendant Group, including testimony of former Defendant Group employees.⁴ Defendants collectively are limited to 80 hours of taking fact deposition testimony upon oral examination, including testimony of former Plaintiff or predecessor or affiliate employees. As an alternative to setting a firm hours limit now, Plaintiffs propose that the parties meet and confer during document production about the scope of necessary deposition testimony and attempt to reach an agreement on the hour limitations for fact depositions; should counsel fail to reach an

⁴ To the extent the same individual is deposed for more than one Defendant Group, there shall be a single deposition.

agreement within 180 days of the date of this Order, the parties will request a status conference with the Court.] [**Defendants' Position:** Plaintiffs collectively are limited to 35 hours of taking fact deposition testimony upon oral examination per Defendant Group, including testimony of former Defendant Group employees.⁵ Defendants collectively are limited to 130 hours of taking fact deposition testimony upon oral examination, including testimony of former Plaintiff employees.] These hour limitations on fact depositions may be enlarged by the Court order upon good cause shown. Separate and apart from these hour limits on fact depositions, Plaintiffs collectively may depose each witness offered as an expert by a Defendant Group, and Defendants collectively may depose each witness offered as an expert by a Plaintiff Group. If a deponent testifies wholly or substantially through an interpreter, the party taking the deposition shall be permitted, on a pro rata basis, two hours of deposition time for each hour spent testifying through the interpreter. For clarity, the hour limitations described in this paragraph do not apply to depositions of third parties or expert witnesses who provide a report under Rule 26(a)(2).

ii. Location of Depositions. The parties shall meet and confer regarding the locations and means (remote or in-person) of depositions.

h. Discovery Matters and Disputes Relating to Protective Orders. Should counsel find they are unable to resolve a discovery matter or a dispute relating to a protective order, the parties involved in the discovery matter or protective order dispute shall contact the Court's Case Manager to schedule an in-person conference/argument. Unless otherwise ordered, by no later than seven business days prior to the conference/argument, any party seeking relief shall file with the Court a letter, not to exceed three pages, outlining the issues in dispute and its position on those issues.

⁵ To the extent the same individual is deposed for more than one Defendant Group, there shall be a single deposition.

By no later than five business days prior to the conference/argument, any party opposing the application for relief may file a letter, not to exceed three pages, outlining that party's reasons for its opposition. A party should include with its letter a proposed order with a detailed issue-by-issue ruling such that, should the Court agree with the party on a particular issue, the Court could sign the proposed order as to that issue, and the opposing party would be able to understand what it needs to do, and by when, to comply with the Court's order. Any proposed order shall be e-mailed, in Word format, simultaneously with filing to rga_civil@ded.uscourts.gov. Should any document(s) be filed under seal, a courtesy copy of the sealed document(s) must be provided to the Court within one hour of e-filing the document(s).

If a discovery-related motion is filed without leave of Court, it will be denied without prejudice to the moving party's right to bring the dispute to the Court through the discovery dispute procedure herein.

i. Other Proceedings. Other than the above-captioned actions, the parties are not presently involved in any pending or completed litigation or inter partes review proceeding concerning any of the patents-in-suit. No Defendant Group has filed any IPR regarding a patent asserted in this case. The statutory deadline under 35 U.S.C. § 315(b) for each Defendant to file an IPR is as follows: for Alembic Pharmaceuticals Limited, February 7, 2023; for Natco Pharma Limited and Natco Pharma, Inc., February 7, 2023; for Cipla Limited and Cipla USA, Inc., February 8, 2023; for MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited, February 8, 2023; and for Sandoz Inc., February 8, 2023.

5. Application to Court for Protective Order. Should counsel find it necessary to apply to the Court for a protective order specifying terms and conditions for the disclosure of confidential information, counsel should confer and attempt to reach an agreement on a proposed form of an

order and submit it to the Court within 60 days of the date of this Order. Should counsel fail to reach an agreement on a proposed form of an order, counsel must follow the discovery dispute procedure set forth in Paragraph 4(h) above. Any proposed protective order must include the following paragraph:

Other Proceedings: By entering this order and limiting the disclosure of information in this case, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or party subject to this order who becomes subject to a motion to disclose another party's information designated as confidential pursuant to this order shall promptly notify that party of the motion so that the party may have an opportunity to appear and be heard on whether that information should be disclosed.

6. Papers Filed under Seal. When filing papers under seal, counsel shall deliver to the Clerk the required number of copies as directed in Paragraph 7 below. A redacted version of any sealed document shall be filed electronically within seven days of the filing of the sealed document.

7. Courtesy Copies. The parties shall provide to the Court two courtesy copies of all briefs and one courtesy copy of any other document filed in support of any briefs (i.e., appendices, exhibits, declarations, affidavits, etc.). This provision also applies to papers filed under seal.

8. Claim Construction Issue Identification. On or before February 6, 2023, the parties shall exchange a list of those claim term(s)/phrase(s) that they believe need construction and their proposed claim construction of those term(s)/phrase(s). This document will not be filed with the Court. Subsequent to exchanging that list, the parties will meet and confer to prepare a Joint Claim Construction Chart to be filed no later than February 27, 2023. The Joint Claim Construction Chart, in Word format, shall be e-mailed simultaneously with filing to rga_civil@ded.uscourts.gov. The parties' Joint Claim Construction Chart should identify for the Court the term(s)/phrase(s) of the claim(s) in issue, and should include each party's proposed

construction of the disputed claim language with citation(s) only to the intrinsic evidence in support of their respective proposed constructions. A copy of the patent(s) in issue as well as those portions of the intrinsic record relied upon shall be submitted with this Joint Claim Construction Chart. In this joint submission, the parties shall not provide argument.

9. Claim Construction Briefing.⁶ Plaintiffs shall serve, but not file, their opening brief, not to exceed 5,000 words, on April 3, 2023. Defendants shall serve, but not file, their answering brief, not to exceed 7,500 words, on May 15, 2023. Plaintiffs shall serve, but not file, their reply brief, not to exceed 5,000 words, on June 19, 2023. Defendants shall serve, but not file, their sur-reply brief, not to exceed 2,500 words, on July 24, 2023. No later than July 31, 2023, the parties shall file a Joint Claim Construction Brief. The parties shall copy and paste their unfiled briefs into one brief, with their positions on each claim term in sequential order, in substantially the form below.

JOINT CLAIM CONSTRUCTION BRIEF

- I. Representative Claims
- II. Agreed-upon Constructions
- III. Disputed Constructions

⁶ As each brief is written and provided to the opposing party, the individual responsible for verifying the word count will represent to the other party that it has so verified and by what means. These verifications should not be provided to the Court unless a dispute arises about them. Pictures, Figures copied from the patent, and other illustrations do not count against the word limit. However, footnotes and endnotes count towards the word limit. Plaintiffs should include with its opening brief one or more representative claims with the disputed terms italicized. Should Defendants want to add additional representative claims, Defendants may do so. The representative claims and the agreed-upon claim constructions do not count against the word limits.

A. [TERM 1]⁷

1. Plaintiffs' Opening Position
2. Defendants' Answering Position
3. Plaintiffs' Reply Position
4. Defendants' Sur-Reply Position

B. [TERM 2]

1. Plaintiffs' Opening Position
2. Defendants' Answering Position
3. Plaintiffs' Reply Position
4. Defendants' Sur-Reply Position

The parties need not include any general summaries of the law relating to claim construction. If there are any materials that would be submitted in an appendix, the parties shall submit them in a Joint Appendix.

10. Hearing on Claim Construction. Beginning at ___ a.m. on August __, 2023, the Court will hear argument on claim construction. Absent prior approval of the Court (which, if it is sought, must be done so by joint letter submission no later than the date on which answering claim construction briefs are due), the parties shall not present testimony at the argument, and the argument shall not exceed a total of three hours. When the Joint Claim Construction Brief is filed, the parties shall simultaneously file a motion requesting the above scheduled claim construction hearing, state that the briefing is complete, and state how much total time the parties are requesting that the Court should allow for the argument.

11. Disclosure of Expert Testimony.

a. Expert Reports. For the party who has the initial burden of proof on the subject matter, its initial Federal Rule 26(a)(2) disclosure of expert testimony is due on or before

⁷ For each term in dispute, there should be a table or the like setting forth the term in dispute and the parties' competing constructions. The table does not count against the word limits.

April 22, 2024. Plaintiffs' responsive reports, including Plaintiffs' expert reports regarding objective indicia of nonobviousness, and Defendants' responsive reports are due on or before June 10, 2024. Reply expert reports limited to Defendants' responses on objective indicia of nonobviousness are due on or before August 19, 2024. No other expert reports will be permitted without either the consent of all parties or leave of the Court. If any party believes that an expert report does not comply with the rules relating to timely disclosure or exceeds the scope of what is permitted in that expert report, the complaining party must notify the offending party within one week of the submission of the expert report. The parties are expected to promptly try to resolve any such disputes and, when they cannot reasonably be resolved, use the discovery dispute procedure set forth in Paragraph 4(h) above; or else the complaint will be waived. By September 13, 2024 the parties shall advise of the dates and times of their experts' availability for deposition. Depositions of experts shall be completed on or before December 17, 2024.

b. Objections to Expert Testimony. To the extent any objection to expert testimony is made pursuant to the principles announced in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), as incorporated in Federal Rule of Evidence 702, it shall be made by motion no later than January 31, 2025 unless otherwise ordered by the Court.

12. Applications by Motion. Except as otherwise specified herein, any application to the Court shall be by written motion. Any non-dispositive motion should contain the statement required by Local Rule 7.1.1.

13. Case Dispositive Motions. There being no issues triable to a jury in this case at this time, no dispositive motions shall be filed without leave of Court.

14. Pretrial Conference. On February/March ___, 2025, the Court will hold a Rule 16(e) final pretrial conference in Court with counsel beginning at ___ a.m. The parties shall file a

joint proposed final pretrial order in compliance with Local Rule 16.3(c) no later than 5 p.m. on the fourth business day before the date of the final pretrial conference. Unless otherwise ordered by the Court, the parties shall comply with the timeframes set forth in Local Rule 16.3(d) for the preparation of the proposed joint final pretrial order.

15. Motions in Limine. Motions *in limine* shall be separately filed, with each motion containing all the argument described below in one filing for each motion. Any supporting documents in connection with a motion *in limine* shall be filed in one filing separate from the motion *in limine*. Each party shall be limited to three *in limine* requests, unless otherwise permitted by the Court. The *in limine* request and any response shall contain the authorities relied upon; each *in limine* request may be supported by a maximum of three pages of argument and may be opposed by a maximum of three pages of argument, and the party making the *in limine* request may add a maximum of one additional page in reply in support of its request. If more than one party is supporting or opposing an *in limine* request, such support or opposition shall be combined in a single three-page submission (and, if the moving party, a single one-page reply). No separate briefing shall be submitted on *in limine* requests, unless otherwise permitted by the Court.

16. Trial. This matter is scheduled for a five-day⁸ bench trial on invalidity arguments, with an additional one-day bench trial for each Defendant Group's non-infringement arguments to the extent non-infringement issues remain, with trial days from 8:30 a.m. to 5:00 p.m. beginning on March/April ____, 2025.⁹ The trial will be timed, as counsel will be allocated a total number of hours in which to present their respective cases.

⁸ Given that the patents-in-suit include claims to compounds, polymorphs, and methods of use, the parties anticipate presenting testimony from multiple experts.

⁹ An unchallenged Orange Book listed patent, U.S. Patent No. 7,459,554, expires on November 24, 2026.

17. Service by E-Mail. The parties consent to service by e-mail, in accordance with Federal Rule of Civil Procedure 5(b)(2)(E). The parties agree that service on any party by e-mail shall be made on both Delaware and lead counsel for that party.¹⁰

UNITED STATES DISTRICT JUDGE

¹⁰ In the following pages the parties have added their respective summary tables of major deadlines in the proposed scheduling order, in case the Court finds them useful.

SUMMARY OF PROPOSED CASE SCHEDULE

Plaintiffs' Proposed Date/Deadline	Defendants' Proposed Date/Deadline	Event
May 9, 2022 at 3:00 p.m.		Parties to file joint proposed Scheduling Order
May 11, 2022 at 3:00 p.m.		Rule 16(b) scheduling conference
45 days after entry of Scheduling Order		Plaintiffs' identification of accused products and asserted claims and production of file histories (paragraph 4(a) of the Default Standard for Discovery, Including Discovery of Electronically Stored Information ("Default Standard"))
60 days after entry of Scheduling Order		Parties to exchange their initial disclosures under Federal Rule of Civil Procedure 26(a)(1)
45 days after service of Plaintiffs' Paragraph 4(a) disclosures		Defendants' production of their respective ANDAs (paragraph 4(b) of the Default Standard)
45 days after service of Plaintiffs' Paragraph 4(a) disclosures		Parties to exchange initial disclosures under Paragraph 3 of the Default Standard
45 days after service of Defendants' Paragraph 4(b) disclosures		Plaintiffs' Initial Infringement Contentions (paragraph 4(c) of the Default Standard)
45 days after service of Plaintiffs' Paragraph 4(c) disclosures		Defendant's Initial Invalidity Contentions
January 9, 2023	December 15, 2023	Any motions to join other parties or amend pleadings due
February 6, 2023		Parties to exchange lists of claim terms/phrases and proposed constructions
February 27, 2023		Parties to file a Joint Claim Construction Chart
April 3, 2023		Plaintiffs to serve opening Claim Construction brief
May 15, 2023		Defendants to serve answering Claim Construction brief
June 12, 2023		Substantial completion of document productions
June 19, 2023		Plaintiffs to serve reply Claim Construction brief

July 24, 2023	Defendants to serve sur-reply Claim Construction brief
July 31, 2023	Parties to file a Joint Claim Construction Brief, and a motion requesting claim construction hearing
August 2023 (Date and time TBD)	Claim Construction Hearing
February 12, 2024	Fact discovery cut-off
April 22, 2024	Initial Rule 26(a)(2) disclosure of expert testimony due for party bearing initial burden of proof on subject matter
June 10, 2024	Plaintiffs' responsive reports due and Defendants' responsive reports due
August 19, 2024	Reply expert reports due
September 13, 2024	Parties to exchange dates and times of their experts' availability for deposition
December 17, 2024	Parties to complete depositions of experts
January 31, 2025	Any <i>Daubert</i> motions due
Date and time TBD in March 2025	Parties to file joint proposed final pretrial order (fourth business day before date of final pretrial conference)
February/March 2025 (Date and time TBD)	Rule 16(e) final pretrial conference
March/April 2025 (Date and time TBD)	Trial: five-day bench trial on invalidity, with additional one-day bench trial for each Defendant Group's non-infringement arguments